

United States agent as part of its initial and updated registration information in accordance with subpart B of this part. Each foreign establishment shall designate only one United States agent and may designate the United States agent to act as its official correspondent.

(1) The United States agent shall reside or maintain a place of business in the United States.

(2) Upon request from FDA, the United States agent shall assist FDA in communications with the foreign establishment, respond to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign establishment. If the agency is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment.

(3) The foreign establishment or the United States agent shall report changes in the United States agent's name, address, or phone number to FDA within 10-business days of the change.

(c) No device may be imported or offered for import into the United States unless it is the subject of a device listing as required under subpart B of this part and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment; however, this restriction does not apply to devices imported or offered for import under the investigational use provisions of part 812 of this chapter.

(d) The device establishment registration and device listing information shall be in the English language.

[66 FR 59160, Nov. 27, 2001, as amended at 77 FR 45944, Aug. 2, 2012]

§ 807.41 Identification of importers and persons who import or offer for import.

(a) Upon initial registration, annually, and at the time of any changes, each foreign establishment required to register and list as provided in § 807.40(a) must, using the FDA elec-

tronic device registration and listing system, submit the name, address, telephone and fax numbers, email address, and registration number, if any has been assigned, of any importer (defined in § 807.3(x)) of the establishment's devices that is known to the foreign establishment. The foreign establishment must also specify which of the establishment's listed products each importer receives from the foreign establishment.

(b) Upon initial registration, annually, and at the time of any changes, each foreign establishment required to register and list as provided in § 807.40(a) must, using the FDA electronic device registration and listing system, submit the name, address, telephone and fax numbers, email address, and registration number, if any has been assigned, of each person who imports or offers for import the establishment's devices into the United States. The term "person who imports or offers for import," which is defined in § 807.3(y), includes agents, brokers, or other parties used by the foreign establishment to facilitate the import of its device into the United States.

(c) For each individual or organization identified by the foreign establishment under paragraphs (a) and (b) of this section, the foreign establishment must submit to FDA electronically the current FDA premarket submission number and any other identifying information that is known to the establishment for each device being imported or offered for import by the named individuals or organizations.

[77 FR 45944, Aug. 2, 2012]

Subpart D—Exemptions

§ 807.65 Exemptions for device establishments.

The following classes of persons are exempt from registration in accordance with § 807.20 under the provisions of section 510(g)(1), (g)(2), and (g)(3) of the act, or because the Commissioner of Food and Drugs has found, under section 510(g)(5) of the act, that such registration is not necessary for the protection of the public health. The exemptions in paragraphs (d), (e), (f), and (i) of this section are limited to those classes of persons located in any State

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as defined in section 201(a)(1) of the act.

(a) A manufacturer of raw materials or components to be used in the manufacture or assembly of a device who would otherwise not be required to register under the provisions of this part.

(b) A manufacturer of devices to be used solely for veterinary purposes.

(c) A manufacturer of general purpose articles such as chemical reagents or laboratory equipment whose uses are generally known by persons trained in their use and which are not labeled or promoted for medical uses.

(d) Licensed practitioners, including physicians, dentists, and optometrists, who manufacture or otherwise alter devices solely for use in their practice.

(e) Pharmacies, surgical supply outlets, or other similar retail establishments making final delivery or sale to the ultimate user. This exemption also applies to a pharmacy or other similar retail establishment that purchases a device for subsequent distribution under its own name, e.g., a properly labeled health aid such as an elastic bandage or crutch, indicating “distributed by” or “manufactured for” followed by the name of the pharmacy.

(f) Persons who manufacture, prepare, propagate, compound, or process devices solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution.

(g) [Reserved]

(h) Carriers by reason of their receipt, carriage, holding or delivery of devices in the usual course of business as carriers.

(i) Persons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer (i.e., patient, physician, layman, etc.) with a device or the benefits to be derived from the use of a device; for example, a hearing aid dispenser, optician, clinical laboratory, assembler of diagnostic x-ray systems, and personnel from a hospital, clinic, dental laboratory, orthotic or prosthetic retail facility, whose primary responsibility to the ultimate consumer is to dispense or pro-

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vide a service through the use of a previously manufactured device.

[42 FR 42526, Aug. 23, 1977, as amended at 58 FR 46523, Sept. 1, 1993; 61 FR 44615, Aug. 28, 1996; 65 FR 17136, Mar. 31, 2000; 66 FR 59160, Nov. 27, 2001]

Subpart E—Premarket Notification Procedures

§ 807.81 When a premarket notification submission is required.

(a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:

(1) The device is being introduced into commercial distribution for the first time; that is, the device is not of the same type as, or is not substantially equivalent to, (i) a device in commercial distribution before May 28, 1976, or (ii) a device introduced for commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II.

(2) The device is being introduced into commercial distribution for the first time by a person required to register, whether or not the device meets the criteria in paragraph (a)(1) of this section.

(3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.

(ii) A major change or modification in the intended use of the device.